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EXAMINER	
185	
ART UNIT	PAPER NUMBER
	7

DATE MAILED: 05/15/91

This is a communication from the examiner in charge of your application
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice re Patent Drawing, PTO-948.
3. ☒ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, Form PTO-152
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____.

Part II SUMMARY OF ACTION

1. ☒ Claims 1-25 are pending in the application.
   Of the above, claims 1-7, 20-25 are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 8-19 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☒ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____ ; filed on _____.
13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

Claims 1-25 are pending in the instant application.

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-3, 7, 20-25, drawn to a polypeptide exhibiting monocyte chemotactic activity, a method for obtaining said protein, and a pharmacological composition containing said protein, classified in Class 530, subclass 324.

II. Claim 4, drawn to a method of isolating a monocyte chemotactic polypeptide, classified in Class 530, subclass 344.

III. Claim 5, drawn to a method of treating infection comprising the administration of a monocyte chemotactic protein, classified in Class 514, subclass 12.

IV. Claim 6, drawn to a method of treating neoplasms comprising the administration of a monocyte chemotactic protein, classified in Class 514, subclass 12.

V. Claims 8-19, drawn to a cDNA sequence encoding a monocyte chemotactic protein, vectors containing said sequence, host cells containing said vectors, and a method of producing said protein via recombinant methods, classified in Class 435, subclass 69.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of

the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. § 806.05(f)). In the instant case the product as claimed (a monocyte chemotactic factor) can be made by a materially different process such as in vitro chemical synthesis (i.e. in vitro translation of mRNA) or isolated by a different process (i.e. a different type of column or the use of immunological methods).

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the process as claimed (treatment of an infection) can be practiced with another materially different product such as antibiotics and/or anti-inflammatory drugs.

Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a

materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the process (treatment of neoplasms) as claimed can be practiced with another materially different product such as an anti-cancer drug or a drug known to inhibit neoplasms.

Inventions I and V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. § 806.05(f)). In the instant case the product as claimed (a monocyte chemotactic polypeptide) can be made by materially different processes such as in vitro synthesis from mRNA transcripts or may be isolated from cells that produce said protein constitutively (i.e. cell line cultures).

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Mr. Gerald Murphy on October 3, 1990, a provisional election was made with traverse to prosecute the invention of Group V, claims 8-19. Affirmation of this election must be made by applicant in responding to this

Office action. Claims 1-7 and 20-25 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

The use of the trademark LAMBDA ZAP II has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9-19 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to the sequence of a human monocyte chemoattractant peptide, as disclosed by applicants. See M.P.E.P. §§ 706.03(n) and 706.03(z).

Claims 9 and 11 refer to a "bioequivalent thereof". Claim 10 refers to "a mutation or variation" in the cDNA. Applicants have disclosed and enabled a particular sequence of a human monocyte chemoattractant peptide. To include variations of said peptide in the claims is beyond the scope of the invention as enabled in the specification.

Claims 9-19 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 9 and 11 are drawn to a nucleotide sequence or "a bioequivalent thereof". It is unclear what applicants intend by this phrase. Is a bioequivalent a compound which possesses the same activity, a sequence variation, a structural variation, or is related in another way to the parent polypeptide? Proper clarification is required.

Claim 10 is drawn to a "mutation or variation" in the cDNA sequence, the meaning of which is vague. It is uncertain what

this claim encompasses, i.e. does this mean additional DNA sequences, a truncated form of the sequence, a leader sequence(s), or something else?

Claim 17 is directed to a microorganism containing a recombinant lambda ZAP II vector. It is understood that lambda phage vectors will function only in E. coli host cells. This claim does not place any limitations on the type of host cell to be used with said vector. It is, therefore, unclear how said vector will function in a microorganism other than E. coli.

Claims 18 and 19 are drawn to a method of producing the disclosed polypeptide "under conditions that allow for expression". This phrase is indefinite because it is unclear what limitations may exist for proper recombinant synthesis of the protein. For example, does the protein have any temperature or other environmental requirements or will any organism synthesize a functional protein?

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claims 9-19 are rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over Ramb, et al.

Ramb describes the isolation of a 12.5 kDa protein from human peripheral blood lymphocytes. This protein was shown to possess chemotactic activities for human monocular phagocytes. The sequence of the protein is not disclosed; however, it would not be difficult for one skilled in the art to identify the

sequence of an isolated protein.

Claims 9-19 are rejected under 35 U.S.C. § 102(a) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over Valente, et al.

Valente also describes a protein possessing monocyte chemotactic activity. This protein (14,500 kDa) was isolated from baboon aortic smooth muscle cells but displayed chemotactic activities for human peripheral blood mononuclear cells. Valente does not disclose the sequence of this protein, but the sequence could be easily obtained by one skilled in the art.

Claims 9-19 are rejected under 35 U.S.C. § 103 as being unpatentable over Yoshimura, et al.

Yoshimura describes two human monocyte chemoattractants 13 and 15 kDa in size. As with the proteins described by Ramb and Valente, the sequence of the protein described by Yoshimura could be obtained by one skilled in the art.

The above references (Ramb, Valente, and Yoshimura) disclose proteins of approximately the same size which possess chemotactic activity for human monocytic cells, and thus appear to discuss the same protein. The instant references therefore anticipate a human monocyte chemoattractant peptide, the sequence of which is described in the instant application.

In the alternative having isolated a protein with chemotactic effects, it would have been obvious and rather

straight-forward to one skilled in the art to identify the sequence and to clone the protein. Sequencing and cloning techniques are well-known and readily available in the art. (See for example Maniatis, Molecular Cloning: A Laboratory Manual.) Therefore, the invention as claimed, is rendered obvious by the prior art. The motivation for sequencing and cloning said protein would have been to obtain large quantities of the protein for further study and possible use as a therapeutic agent.

Any inquiry concerning this communication should be directed to Dian Cook at telephone number (703) 308-4229.

RICHARD A. SCHWARTZ
SUPERVISORY PATENT EXAMINER
ART UNIT 185